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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,756	10/05/2001	Michael G. Katze	A-70383-2/RMS/AXG	5359

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EXAMINER	
VOGEL, NANCY T	
ART UNIT	**PAPER NUMBER**
1636	11

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/972,756	KATZE ET AL.	
	Examiner	Art Unit	
	Nancy Vogel	1636	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-29 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-29 are pending in the case. Receipt of Preliminary amendments on 19/5/01, 7/18/02 and 1/23/03 is acknowledged.

Claim Objections

Claims 1-29 are objected to because of the following informalities: abbreviations such as "PKR" should be spelled out. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11, 13, 14, and 17-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,326,151. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods rely upon the same mechanism of action or operation, and are significantly overlapping in scope.

Claims 1-11, 13, 14, and 17-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,030,785. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods rely upon the same mechanism of action or operation, and are significantly overlapping in scope.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. .

The following factors have been considered in the present rejection:

The nature of the invention: The instant method is drawn to a method of inhibiting the development of the recited class of malignancies in vivo. This encompasses not only methods of treatment of existing malignancies to prevent further progression thereof, but also prevention of the occurrence of new malignancies.

Prevention of new malignancies would required that all cells in the patient which could possibly become malignant have taken up the recited antisense molecule, and that said antisense molecule would be effective to stop the transition to a malignant state. Thus, nearly all cells in the patient would be subject to whatever degree of toxicity that would be caused by the antisense.

The state of the prior art, and the predictability or unpredictability of the art.

Branch (TIBS Vol. 23, pp. 45-50, 1988) teaches, e.g. as summarized in the Abstract, that as of 1998, no clear demonstration of an antisense molecule acting as an antisense against the intended single target gene had been made. Clearly, as of that date, use of antisense agents in the treatment of pathologies in patients was far from routine; it was essentially non-existent. Branch also shows that mere knowledge of a potential target gene does not predict that an antisense treatment of a pathology involving that target gene would be within routine skill in the art, and that unwanted toxic side effects are problematic. Gura (Science, Vol. 278, pp. 1040-1042 , 1997) shows, generally, that in vitro and animal model systems were not regarded in late 1997 as reliable predictors of clinical success for potential therapeutics tested in those systems.

The amount of direction or guidance presented in the specification, and the presence or absence of working examples.

Applicants have not presented a working example of treatment with an antisense as recited in the instant claim. Further, no guidance specific for treatment with such an antisense molecule, with respect to modes of delivery, dosage regimens, et cetera, has been presented. Only general guidance has been set forth.

The art of treatment of pathological conditions in patients using antisense molecules was clearly not routine as of the filing date of the present invention. Indeed, no real successes had been known in the art. Applicants have not overcome this lack of guidance from the art with teachings of a specific nature in the specification, with regards to treatment regimens, et cetera. As such, one of skill in the art, attempting to have practiced the claimed invention, would have been forced to turn to empirical experimentation to develop a useable antisense molecule, formulate it as a therapeutic, and develop a treatment regimen for use of such a composition. As noted supra, this task is made even more difficult for prophylactic methods, in that essentially all cells which might eventually become diseases must be treated successfully. In view of the complete failure of the prior art to achieve such successful treatment, and the opinion of workers in the art that multiple problems in achieving success were presented and unsolved, the experimentation required to achieve success would have been deemed undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-11, 15-17 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-11 provide for the use (apparently) of the recited yeast cell, but, since the claim does not set forth any steps involved in the method/process, it is unclear what

method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-11 are drawn to a "method ...comprising a yeast cell". However, a method can only comprise steps in said method. It would appear that the instant claims were intended to be drawn to a method of using (or the a use of, as set forth supra) the recited yeast.

Claims 9-11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 15-17 are vague and indefinite in the recitation of "wherein said difference in said property is determined by assaying a decreased level..."(claim 15) "wherein said difference in said property is determined by assaying an increase in the level of dimerization" (claim 16), and "wherein said difference in said property is determined by assaying an increase in the level..." (claim 17). Presumably, the level in the presence of a candidate agent is determined, and then compared with the level in the absence of a candidate agent, and a decreased or increased level indicates the ability of the candidate agent to modulate binding or interaction o NS5A to PKR. This should be clarified in the claims.

Claim 21 is vague and indefinite in its recitation of "said PKR protein kinase polypeptide is selected from a group consisting of p68...and e1F-1 kinase". According to the specification at page 7, last paragraph, the terms recited in the claim are alternative names for the PKR kinase. Clarification is required.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

NTV
9/24/03

JAMES KETTER
PRIMARY EXAMINER